

## CLAIMS

1. Complexes formed by cationic liposomes and by polydeoxyribonucleotides having a molecular weight in the range 7,000-60,000 Da, preferably 10,000-60,000 Da, obtainable by depolymerization of nucleic acids, wherein the polydeoxyribonucleotides are located on the outer surface of the liposome, for use as a medicament.

- B* 2. ~~Complexes~~ according to claim 1 ~~for preparing medicaments~~ having an anti-inflammatory activity.

- B* 3. ~~Complexes~~ according to claim 1 ~~for preparing medicaments~~ having an anti-thrombotic activity.

- B* 4. ~~Complexes~~ according to claim 1 ~~for preparing medicaments~~ having an anti-hypertensive activity.

- B* 5. ~~Complexes~~ according to claim 1 ~~for preparing medicaments~~ for the therapy of pathologies the treatment of which requires a sustained release of the endothelial prostacyclin.

- B* 6. ~~Complexes~~ according to ~~claims 1-5~~ wherein the polydeoxyribonucleotide is defibrotide.

- B* 7. ~~Complexes~~ according to claim 6 wherein the polydeoxyribonucleotide has a molecular weight in the range 15,000-30,000.

8. Complexes according to ~~claims 1-7~~ wherein one or more antioxidants preferably alphotocopherol are added.

- Claim 1*
- The Pharmaceutical Formulation*
9. ~~Complexes~~ according to ~~claims 1-8~~ wherein cationic surfactants containing one or more mono-, di-substituted amminic groups, or quaternary ammonium groups, are present, said quaternary ammonium groups containing one or more aliphatic chains with a number of carbon atoms ranging from 8 to 22, ~~preferably said cationic surfactants are quaternary ammonium surfactants having aliphatic chains with 18 carbon atoms.~~

- The Pharmaceutical Claim Formulation*
10. ~~Complexes~~ according to ~~claims 1-9~~ wherein the molar ratio between the total amount of the liposome lipid(s) and cationic surfactant ranges from 10:0.05 to 10:3, ~~preferably being 10:1.~~

11. Complexes according to claim 10 wherein, together with the phosphatidylcoline (or phosphatidylethanolamine) there is a second and different lipid and the molar ratio phosphatidylcoline (or phosphatidylethanolamine): second lipid: surfactant ranges from 9:1:0.05 to 7:3:3, preferably 8:2:1.

- The Pharmaceutical Formulation Claim 1*
12. ~~Complexes~~ according to ~~claims 1-11~~ wherein the weight ratio between the liposome amount and the active principle ranges from 10:2 to 10:0.1, ~~preferably is 10:1.~~

- Claim 1*
13. Complexes according to ~~claims 1-12~~ obtainable by a process comprising the following steps:

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- a. liposome preparation by mixing 4 parts of polar or apolar organic phase, wherein are solubilized the lipids, the cationic surfactant and the antioxidant, with 1 part of water, then subjecting the obtained biphasic system to sonication at 0°C for 5-20 minutes and evaporating the organic phase at room temperature at a reduced pressure, thus forming an emulsion;
  - b. flowing said emulsions through a polycarbonate membrane having a pore diameter ranging from 100 to 600 nm, preferably 400 nm, said step repeated for at least three times,
  - c. lyophilizing the emulsion after addition of an aqueous solution of a lyophilizing coadjuvant, so that the amount of said coadjuvant is in excess of at least 7 times with respect to that of the lipids, the excess preferably ranging from 10 to 15 times,
  - d. preparing the emulsion for pharmaceutical use by adding in a sterile environment under stirring a diluted sterile isotonic aqueous solution of polydeoxyribonucleotides to the vessel containing the lyophilizate, or alternatively by adding a sterile isotonic solution to the vessel containing the lyophilized liposome and the thus obtained emulsion mixed in a sterile environment with the solution containing the active principle.

Claim 1

14. Complexes according to ~~claims 1-13~~ contained in pharmaceutical formulations for parenteral administration.

Claim 1

15. Use of the complexes according to ~~claims 1-14~~ for the preparation of medicament having antiinflammatory activity.

Claim 1

16. Use of the complexes according to ~~claims 1-14~~ for the preparation of medicament having antithrombotic activity.

17. Use of the complexes according to claims 1-14 for the preparation of medicament having antihypertensive activity.

Claim 1

18. Use of the complexes according to ~~claims 1-14~~ for the preparation of medicament for treating pathologies which require a sustained release of the endothelial prostacyclin.

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